

REMARKS

This paper is being filed in response to the Office Action dated May 7, 2003. Applicants respectfully request reconsideration of the above-identified application in light of the amendments and remarks presented in the instant Amendment.

Claims 1-4, 6-9, 13, 15-22, 24, 25, 27, 28 and 31-36 were pending and subject to examination. Claims 1-4, 6-9, 13, 15-22, 24-25, 27-28, and 31-36 are rejected under the second paragraph of 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claims 1-4, 6-9, 13, 15-22, 24-25, 27-28, and 31-36 are rejected under the first paragraph of 35 U.S.C. § 112 for lack of enablement.

Applicants herein amend Claims 1-4, 6-9, 13, 15-22, 27-28, 31-32, and 34-36 as indicated. Support for the amendments to Claims 1-4, 6-9, 13, 15-22, 27-28, 31-32, and 34-36 are found in the specification, *inter alia*, on lines 6-12 of page 4. Applicants also cancel Claims 24, 25 and 33 without disclaimer or prejudice to the prosecution of the subject matter of these claims in subsequent divisional or continuation patent applications. New Claim 37 is added. Support for Claim 37 may be found in the specification, *inter alia*, on p. 9, line 26 through p. 10, line 2. Thus, Claims 1-4, 6-9, 13, 15-22, 27, 28, 31-32 and 33-37 are pending subject to the entry of this amendment.

For reasons set forth below, Applicants respectfully request that the rejections be removed and these claims be allowed to issue.

I. The Claims Are Definite

Claims 1-4, 6-9, 13, 15-22, 24-25, 27-28, and 31-36 are rejected under 35 U.S.C. §112, second paragraph as indefinite for allegedly failing to particularly point out and distinctly claim

the subject matter that the Applicant regards as the invention. Specifically, the Examiner alleges that the claims are indefinite in containing a recitation of "Xaa" to designate NH₂ or OH moieties, which are not amino acids. In addition, the Examiner asserts that the recitation of the phrase "0-5" with regard to the number of amino acids that could be contained in a variable region renders the claims indefinite because "0 amino acids does not make sense."

In response, Applicants disagree with the Examiner's assertion that the phrase "0-5 amino acids" does not make sense. Applicants intention with the original claim language was to claim those peptides of general formula I in which the Cysteine residue at position 12 could be either the terminal residue of the peptide being claimed or be followed by as many as five additional amino acid residues. Thus, it is certainly possible to have a symbol ("Xaa") that represents a variable number of elements as being capable of representing an absence of elements as well.

However, in order to advance the prosecution of this application and to bring greater clarity to the claims, and without conceding the merit of the Examiner's position, Applicants have amended Claims 1, 13, 16, 19, 28, 34 to remove the phrase in question, as well as the use of the term "Xaa" to refer to NH₂ or OH moieties. Applicants assert that the claims, as amended herein, are clear and definite. Applicants, therefore, respectfully request withdrawal of this rejection.

II. The Claims Are Enabled

Claims 1-4, 6-9, 13, 15-22, 24-25, 27-28, and 31-36 are rejected under the first paragraph of 35 U.S.C. § 112 for lack of enablement. According to the Examiner, the specification, while enabling for the nucleic acid fragment of SEQ ID NO:1 from *Psodius maculiventis* encoding thanatin with bacterial and fungicidal properties when expressed in transformed plants and the sequences of SE ID NOS:2, 4 and 5, is not enabling for an isolated nucleic acid sequence

encoding the amino acid of Claims 1, 13, 16, 19, 28 and 34 having thanatin activity or a complement of the disclosed sequences and a method for using said nucleic acid sequences to induce disease resistance in transgenic plants. Specifically, the Examiner contends that the specification provides no guidance for a nucleic acid sequence encoding a modified peptide comprising Xaa being a variable residue of having from 1 to 10 amino acids and still retaining thanatin disease resistance in plants. To support this contention, the Examiner claims that modifications of terminal regions of a peptide to add one or two amino acid residues while retaining specific enzymatic activity are well within the level of one skilled in the art, but that modifications comprising additions of 1-10 amino acids at the amino terminal end of the peptide and 0-5 amino acids at the carboxy terminal end of the peptide is not because of the "unpredictability" of the art. The Examiner further cites Fehlbaum *et al.* (PNAS 1996;93:1221-1225) in support of this position.

A careful review of Fehlbaum *et al.*, specifically Table 2, confirms that removing amino acid residues from the 21 amino acid thanatin peptide can reduce its antifungal and antibacterial activities. However, this is not the same as the Examiner's contention that the addition of amino acids at the N- or C-terminals of the I11C peptide of Fehlbaum *et al.* will abolish its activity. As Table 2 clearly shows, at least six different peptides may be produced in which the core thanatin peptide of the instant application is extended at the N-terminal, C-terminal or both ends while retaining, and in fact enhancing, anti-fungal and anti-bacterial activity. Thus, Applicants maintain that Fehlbaum *et al.* does not support the position that additions of amino acids to the terminal ends of the thanatin peptide of general formula I claimed herein while retaining its biological efficacy is not within the skill of the ordinary artisan in the field.

The Examiner further contends that undue experimentation would be required for one of ordinary skill to determine which amino acids could be added to the N- and C-terminals of the peptide of general formula I while retaining its anti-fungal and anti-bacterial properties. As noted in *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984), "[t]he fact that some experimentation is necessary does not preclude enablement."

The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *Johns Hopkins University v. Cellpro*, 152 F.3d 1342, 1360 (Fed. Cir. 1998).

Applicants maintain that the specification provides adequate guidance at, *inter alia*, p. 3, line 9 through p. 4, line 12, for those of ordinary skill in the art to both make the additions to the terminal ends of the thanatin peptide taught by the instant application and to confirm that the resulting peptides retain the antibacterial and antifungal activity characteristic of thanatins.

The Examiner also asserts that the specification fails to provide adequate support for a transgenic plant having disease resistance as a result of expression of the exemplified or non-exemplified nucleic acid sequence. Applicants respectfully traverse this contention as well. However, in order to advance the prosecution of this application, and without conceding the merit of the Examiner's position, Applicants have cancelled Claims 24, 25 and 33, which were drawn toward disease resistant plants comprising the nucleic acid encoding a peptide comprising the amino acid sequence of general formula I.

The Examiner also indicates that, in her opinion, the inclusion of the phrase "complement" instead of "fully complementary" in the claims, allows the claims to read on sequences as small as 2-mers, which, not having thanatin activity, are therefore not enabled by the specification. In response, Applicants have amended the relevant claims to replace indicate

that the complementary sequences being claimed are those that are fully complementary to the disclosed sequences.

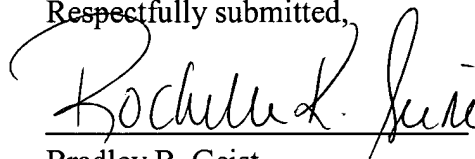
In light of the foregoing arguments and amendments, Applicants assert that the claims are fully enabled by the specification, and respectfully request withdrawal of the rejections under the first paragraph of 35 U.S.C. § 112.

CONCLUSION

Applicants maintain that in view of the amendments and remarks made herein, the claims are in condition for allowance. A Notice of Allowance is earnestly solicited.

Applicants do not believe any fee is required for this filing. Nevertheless, the Commissioner is hereby authorized to charge any fees required for this submission not otherwise enclosed herewith to Deposit Account No. 02-4377. Two copies of this page are enclosed.

Respectfully submitted,

A handwritten signature in cursive script, reading "Rochelle K. Seide", written over a horizontal line.

Bradley B. Geist
Patent Office Reg. No. 27,551

Rochelle K. Seide
Patent Office Reg. No. 32,300

Attorneys for Applicants
30 Rockefeller Center, 45th floor
New York, NY 10112

(212) 408-2626